UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,943	06/29/2007	Rob Short	P-7735	6981
	7590 01/19/201 et, VP & Chief IP Cour	EXAMINER		
Becton, Dickinson and Company			YAKOVLEVA, GALINA M	
(Hoffman & Baron) 1 Becton Drive, MC 110		ART UNIT	PAPER NUMBER	
Franklin Lakes, NJ 07417-1880			1641	
			MAIL DATE	DELIVERY MODE
			01/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Occurrence	10/599,943	SHORT ET AL.			
Office Action Summary	Examiner	Art Unit			
	GALINA YAKOVLEVA	1641			
The MAILING DATE of this communication appo Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
<ul> <li>1) ⊠ Responsive to communication(s) filed on <u>06 December</u></li> <li>2a) ☐ This action is <b>FINAL</b>. 2b) ☒ This</li> <li>3) ☐ Since this application is in condition for allowan closed in accordance with the practice under Expression in the practice of the practic</li></ul>	action is non-final. ce except for formal matters, pro				
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-16,26-29 and 31 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-16, 26-29 and 31 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner	epted or b) $\square$ objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ite			

### **DETAILED ACTION**

Responsive to communications entered 11/05/2010 and 12/06/2010. As of 11/05/2010, Claims 1-16, 26-29 and 31 are pending. Claims 1-16, 26-29 and 31 are examined.

## Priority

The instant application, 10/599,943, is the 35 U.S.C 371 filing of PCT/GB05/01369, filed on 04/07/2005, which claims foreign priority to United Kingdom patent application 0408351.5, filed on 04/15/2004.

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 11/05/2010 and 12/06/2010 have been entered.

# Withdrawn Objections/Rejections

- I. The objection to Claim 26 is withdrawn in view of Applicant's amendment of the claim.
- II. The rejection of Claims 29 and 30 under 35 U.S.C. 102(b) as being anticipated by Short & Whittle, WO 01/031339, as evidenced by WO 98/19161 and Sigma Catalog, 2000-2001, page 337, is withdrawn in view of Applicant's amendment of Claim 29 and cancellation of Claim 30.

Application/Control Number: 10/599,943 Page 3

Art Unit: 1641

III. The rejection of Claims 29 and 30 under 35 U.S.C. 102(e) as being anticipated by Short *et al.*, WO 2004/040308 A1, as evidenced by Dako General ELISA Procedure,

February 2002, is withdrawn in view of Applicant's amendment of Claim 29 and

cancellation of Claim 30.

IV. The rejection of Claim 30 under 35 U.S.C. 103(a) as being unpatentable over

Short & Whittle, WO 01/031339, as evidenced by WO 98/19161, and Sigma Catalog,

2000-2001, page 337, in view of Marchant, WO 94/10938 and Schwarz et al.

Glycobiology, 2003, vol. 13, No. 11, p. 749-754, is withdrawn in view of applicant's

cancellation of the claim.

V. The provisional rejection of Claim 30 on the ground of nonstatutory obviousness-

type double patenting as being unpatentable over Claims 1, 3-25 and 33-38 of co-

pending U.S. Application No. 10/533,063, in view of Schwartz and Sigma; over Claims

85, 87, 90-94, 96, 102, 103, 108, 109 and 112-123 of co-pending U.S. Application No.

10/560,210, in view of Schwartz and Sigma; and over Claims 41, 47-50 and 54 of co-

pending U.S. Application No. 10/509,431, in view of Marchant, Schwartz and Sigma is

withdrawn in view of Applicant's cancellation of Claim 30.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for

patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Page 4

Claims 1, 8-16, 27, 28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Short & Whittle, WO 01/031339, published on May 3, 2001 (IDS entered 01/30/2008) as evidenced by WO 98/19161 (Final Office Action dated 09/08/2010), to which Short & Whittle refer to at page 3, lines 12-15.

The claims, as recited in the sole independent Claim 1, are drawn to a method for the selective disassociation of at least one biological entity from a plasma polymerized surface of an organic monomer including an allylamine, said method comprising contacting said surface with at least one agent having a salt concentration of about 500 mM NaCl to about 2 M NaCl, wherein said agent provides for selective disassociation of said entity from said plasma polymerized surface. Claims 28, 29 and 31 recite the variable ranges within the claimed range of the salt concentration of Claim 1. Claims 2-7 and 26 require the biological entity to be a carbohydrate. Claim 8 requires the biological entity to be a polypeptide. Claims 9-10 and 27 require the biological entity to be a nucleic acid molecule. Claims 12 and 13 require the surface to comprise a plasma polymer of a volatile acid. Claim 14 requires the surface to comprise a plasma polymer of a volatile alcohol. Claim 15 requires the surface to comprise a mixture of volatile acid and volatile hydrocarbon.

**Short & Whittle,** throughout the publication, and, for example, at page 5, line 1; page 8, lines 1-4; page 7, lines 10-14 and 16-17; Claims 8, 11, 13-15, 25; teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for detection of polypeptides, nucleic acids, including DNA and RNA, and cells. Short & Whittle, at page 4, line 21 through page 5, line 6; Claims 16-24; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon.

As to recitation "a salt concentration of about 500 mM NaCl to about 2 M NaCl," at page 12, Short & Whittle teach an enzyme linked immunosorbent assay (ELISA) for estimating the binding of human immunoglobulin G (IgG) onto the different plasma copolymer surfaces. Short & Whittle teach washing the surfaces with PBS-Tween (page 12, lines 14-15). According to MPEP 2131.01, extra references can be used to show the meaning of a term used in the primary reference. WO 98/19161, to which Short & Whittle refer to at page 3, lines 12-15, indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods. See, for example, page 19, line 32; page 22, line 6. A specific example in the prior art which is within a claimed range, here, 0.5 M NaCl concentration, anticipates the range. MPEP 2131.01.

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if *one* of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

Therefore, each and every element of the claims are met by the Short & Whittle reference.

Claims 1-16, 26-28 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Short *et al.*, WO 2004/040308 A1, filed October 29, 2003, published May 13, 2004 (IDS entered 01/30/2008), as evidenced by **Dako** General ELISA Procedure, February 2002 (Final Office Action dated 09/08/2010).

The applied reference has a common inventor(s) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

**Short** *et al.*, throughout the publication, and, for example, at pages 6, 8, and 13, teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for immobilization of carbohydrates, polypeptides, genomic DNA, and cells. Short *et al.* at page 3 through page 5; Claims 4-7; 11-12; 15-16; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon. Short *et al.* at page 1 teach heteropolysaccharide, including glycosaminoglycans, such as, hyaluronan, dermatan

sulfate, chondroitin sulfate, heparin, heparan sulphate and keratan sulphate, and homopolysaccharide.

As to recitation "a salt concentration of about 500 mM NaCl to about 2 M NaCl," Short *et al.* at page 16 teach use of standard ELISA methods to wash the unbound heparin from the allylamine coated microtiter plates. According to MPEP 2131.01, extra references can be used to show the meaning of a term used in the primary reference. **Dako** General ELISA Procedure, February 2002 indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods. A specific example in the prior art which is within a claimed range, here, 0.5 M NaCl concentration, anticipates the range. MPEP 2131.01.

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if *one* of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

Therefore, each and every element of the claims are met by the Short *et al.* reference.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 26-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, WO 01/031339, published on May 3, 2001 (IDS entered 01/30/2008) as evidenced by WO 98/19161 (Final Office Action dated 09/08/2010), to which Short & Whittle refer to at page 3, lines 12-15, in view of Marchant, WO 94/10938 (Final Office Action dated 09/08/2010) and Schwarz et al. Glycobiology, 2003, vol. 13, No. 11, p. 749-754 (Final Office Action dated 09/08/2010).

The rejection is maintained for the reasons set forth in the Final Office Action dated 09/08/2010.

Claims 1-16, 26-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, WO 01/031339, published on May 3, 2001 (IDS entered 01/30/2008) as evidenced by WO 98/19161 (Final Office Action dated 09/08/2010), to which Short & Whittle refer to at page 3, lines 12-15, in view of Hutchens, WO 98/59360, published 12/30/1998, and Marchant, WO 94/10938, published 05/26/1994 (Final Office Action dated 09/08/2010).

Short & Whittle, throughout the publication, and, for example, at page 5, line 1; page 8, lines 1-4; page 7, lines 10-14 and 16-17; Claims 8, 11, 13-15, 25; teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for detection of polypeptides, nucleic acids, including DNA and RNA, and cells. Short & Whittle, at page 4, line 21 through page 5, line 6; Claims 16-24; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having

functional groups with a hydrocarbon. At page 12, Short & Whittle teach an enzyme linked immunosorbent assay (ELISA) for estimating the binding of human immunoglobulin G (IgG) onto the different plasma copolymer surfaces. Short & Whittle teach washing the surfaces with PBS-Tween (page 12, lines 14-15). **WO 98/19161**, to which Short & Whittle refer to at page 3, lines 12-15, indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods for ELISA methods. See, for example, page 19, line 32; page 22, line 6.

Short & Whittle do not teach the biological entity to be a carbohydrate.

**Hutchens**, throughout the publication, and, for example, in Abstract, teaches methods of retentate chromatography for resolving analytes in a sample, which methods involve adsorbing the analytes to a substrate under a plurality of different selectively conditions, and detecting the analytes retained on the substrate by desorption spectrometry. At page 7, line 9; page 21, line 15; Hutchens teaches the analyte to be an organic biomolecule, such as carbohydrate. At page 33, lines 1-9, Hutchens teaches washing the adsorbent with eluants. At page 33, lines 19-26, Hutchens teaches the use of ionic strength-based salt eluants:

"Eluants which modify the selectivity of the adsorbent with respect to ionic strength include salt solutions of various types and concentrations. The amount of salt solubilized in the eluant solution affects the ionic strength of the eluant and modifies the adsorbent binding ability correspondingly. Eluants containing a low concentration of salt provide a slight modification of the adsorbent binding ability with respect to ionic strength. Eluants containing a high concentration of salt provide a greater modification of the adsorbent binding ability with respect to ionic strength."

At Fig. 2, Hutchens teaches the use of 0.5 M and 1.0 M NaCl eluants:

Neither Short & Whittle nor Hutchens teach using a salt concentration of about 2 M NaCl.

**Marchant,** throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to select a salt concentration of about 500 mM NaCl to about 2 M NaCl from the 3 M NaCl linear salt gradient, taught by Marchant, and the 0.5 M and 1.0 M NaCl eluants, taught by Hutchens, for the selective disassociation of a carbohydrate from a plasma polymerized surface taught by Short & Whittle. Here, the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for the selective disassociation of a biological entity, wherein said entity may be a carbohydrate, because it would be desirable, to re-use the plasma polymerized surface.

taught by Short & Whittle, or use it, for example, for investigation of ionic strength of carbohydrate-protein interactions, as taught by Hutchens.

One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because NaCl is routinely used in the standard ionic strength-based salt eluants, as taught by Hutchens. In addition, as taught by Marchant, use of the 3 M NaCl linear salt gradient elution of increasing ionic strength provides selective separation of carbohydrates, such as heparin polysaccarides.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 26-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 3-25, and 33-38 of copending Application No. 10/533,063 (the '063 application), PGPUB 20060251693 in view of Schwarz et al. Glycobiology, 2003, vol. 13, No. 11, p.

749-754 (Final Office Action dated 09/08/2010) and **Hutchens**, WO 98/59360, published 12/30/1998.

The '063 application claims a method to immobilize at least one type of carbohydrate molecule comprising the steps of: i) providing a monomer source comprising one or more organic compounds which are capable of polymerization; ii) creating a plasma of said monomer source; iii) contacting a surface with said plasma to provide a plasma polymer coated surface; iv) contacting said plasma polymer coated surface with at least one type of biologically active carbohydrate molecule in its native form, wherein the plasma polymer coated surface is not modified prior to contacting with said carbohydrate molecule in its native form; and v) incubating said plasma polymer coated surface with said carbohydrate molecule in its native form, whereby the carbohydrate molecule is passively adsorbed, in the absence of albumin or salts, on the surface and thereby immobilized, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity.

**Schwarz** *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

**Hutchens** teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the '063 application.

Claims 1-16, 26-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 85, 87, 90-94, 96, 102, 103, 108, 109, and 112-123 of copending Application No. 10/560,210 (the '210 application), PGPUB 20060252046 in view of Schwarz et al. Glycobiology, 2003, vol. 13, No. 11, p. 749-754 (Final Office Action dated 09/08/2010) and Hutchens, WO 98/59360, published 12/30/1998.

The '210 application claims a method for preparing a heterogenous binding surface on a substrate comprising: depositing a plasma polymer on the substrate using at least one organic compound monomer as a source of plasma, wherein the monomer is polymerisable, the monomer comprises an alkene containing up to 20 carbon atoms and the monomer has a vapor pressure of at least 6.6x10<sup>2</sup> mbar; and coating at least part of the plasma polymer deposit with a binding entity which comprises a carboxyl or an amine functional group, wherein the binding entity is selected from the group consisting of cells, metabolites, pharmaceutically active agents, proteins including hormones, antibodies, enzyme, receptor, macromolecules RNA, protein fragments. peptides. including DNA, polypeptides. ligands. proteoglycans, carbohydrates, nucleotides, oligonucleotides, toxic reagents and

chemical species and wherein the organic compound monomer is selected from the group consisting of N-vinyl pyrrolidone, allyl alcohol, acrylic acid, octa-I,7-diene, **allyl amine**, perfluorohexane, tetraethyleneglycol monoallyl ether and hexamethyl disiloxane. (Emphasis added).

**Schwarz** *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

**Hutchens** teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the '210 application.

Claims 1-16, 26-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 41, 47-50, and 54 of copending Application No. 10/509,431 (the '**431** application), PGPUB 20060166183 in view of **Marchant**, WO 94/10938 (Final Office Action dated

Application/Control Number: 10/599,943 Page 15

Art Unit: 1641

09/08/2010); **Schwarz** *et al.* Glycobiology, 2003, vol. 13, No. 11, p. 749-754 (Final Office Action dated 09/08/2010) and **Hutchens**, WO 98/59360, published 12/30/1998.

The '431 application claims a method for preparing a plasma polymerized surface on a substrate comprising: depositing a plasma polymer on the substrate using at least one organic compound monomer as a source to produce a plasma which is emitted from a plasma source and from which the plasma polymer is deposited; and moving at least one of: (i) the plasma source, and (ii) the substrate, relative to one another during plasma deposition such that at least part of the substrate has a plasma polymer deposit that is non-uniform, wherein the substrate is separated from the plasma source by a mask plate having at least one aperture that defines features of the deposited plasma polymer surface, the mask plate being spaced from the substrate wherein the organic compound monomer is selected from the group consisting of allyl alcohol, acrylic acid, octa-l,7,-diene, allyl amine, perfluorohexane, tetraethyleneglycol monoalkyl ether or hexamethyldisiloxane. (Emphasis added).

**Marchant**, throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column

separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

**Schwarz** *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

**Hutchens** teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the '413 application.

This is a <u>provisional</u> obviousness-type double patenting rejection.

### Response to Arguments

Applicant's arguments filed on 11/05/2010 have been fully considered but they are not persuasive.

The rejection of Claims 1, 8-16, 27, 28 and 31 under 35 U.S.C. 102(b) as being anticipated by Short & Whittle, as evidenced by WO 98/19161, is maintained. Applicant traversed Short & Whittle for not teaching an agent having a salt concentration of about 500 mM NaCl to about 2 M NaCl, wherein said agent provides for selective

disassociation of said entity from said plasma polymerized surface. As shown above, Short & Whittle, at p. 12, as evidenced by WO 98/19161, anticipate the claimed range of NaCl concentration by teaching an agent having a salt concentration of 500 mM NaCl.

The rejection of Claims 1-16, 26-28 and 31 under 35 U.S.C. 102(e) as being anticipated by Short *et al.*, as evidenced by Dako General ELISA Procedure, February 2002, is maintained. Applicant traversed Short *et al.* for not teaching an agent having a salt concentration of about 500 mM NaCl to about 2 M NaCl, wherein said agent provides for selective disassociation of said entity from said plasma polymerized surface. As shown above, Short *et al.*, as evidenced by Dako General ELISA Procedure, February 2002, anticipate the claimed range of NaCl concentration by teaching an agent having a salt concentration of 500 mM NaCl.

The rejection of Claims 1-16, 26-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, as evidenced by WO 98/19161, in view of Marchant, and Schwarz is maintained for the reasons set forth in the Final Office Action dated 09/08/2010. Applicant traversed Marchant based on their erroneous definition of a linear salt gradient as "an initial salt concentration of a 3 M that increases to a higher ionic strength." The examiner notes that one of the skill in the art would appreciate that a linear salt gradient is defined as a final salt concentration of 3 M NaCl, but not an initial salt concentration, as asserted by Applicants. This is evidenced by Fig. 5 of Yuan et al. "Immobilization of high-affinity heparin oligosaccharides to radiofrequency plasmamodified polyethylene," *J. Biomed. Materials Res.*, 1993, vol. 27, pp. 811-819, (cited solely to address applicant's instant traversal; Advisory Action dated 11/26/2010), which

appears to be a scientific counterpart of the Marchant reference. As to Applicant's traversal of Schwartz, the examiner reiterates that this reference teaches that it is well-known in the art to use eluants with various NaCl concentrations, e.g., 2 M NaCl, for dissociation of biological material from carbohydrate arrays.

As shown above, the provisional rejections of Claims 1-16, 26-29 and 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 3-25 and 33-38 of co-pending U.S. Application No. 10/533,063, in view of Schwartz and Hutchens, WO 98/59360, published 12/30/1998; over Claims 85, 87, 90-94, 96, 102, 103, 108, 109 and 112-123 of co-pending U.S. Application No. 10/560,210, in view of Schwartz and Hutchens, WO 98/59360, published 12/30/1998; and over Claims 41, 47-50 and 54 of co-pending U.S. Application No. 10/509,431, in view of Marchant, Schwartz and Hutchens, WO 98/59360, published 12/30/1998, are maintained. Applicant state that they will consider filing a terminal disclaimer. Therefore these provisional rejections are maintained.

#### Conclusion

Claims 1-16, 26-29 and 31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALINA YAKOVLEVA whose telephone number is (571)270-3282. The examiner can normally be reached on Monday-Friday 8:00 AM-5:00 PM.

Application/Control Number: 10/599,943 Page 19

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Y./

Examiner, Art Unit 1641

/Mark L. Shibuya/

Supervisory Patent Examiner, Art Unit 1641